Heritage Information Systems, Inc.

Clinical Edit Criteria Proposal

Drug/Drug Class: **Botulinum Toxin Type A (Botox) Clinical Edit**
Date: March 30, 2005
Prepared for:
Prepared by: Missouri Medicaid

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose: To control costs by following evidence based medical guidelines to ensure appropriate use of Botox Type A.

Why was this Issue Selected: Botulinum toxin type A has both cosmetic and non-cosmetic FDA-approved uses. Additionally, Botox averages close to $1300.00 per prescription. This clinical edit is designed to assure prudent prescribing of this agent for non-cosmetic uses only.

Program-specific information:

Drug	Claims	Expense
• Botulinum Injection	*304*	*$533,933*

Setting & Population: All patients.

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Non-Preferred Agent** ☒ **Appropriate Indications** ☐

Data Sources: ☒ **Only administrative databases** ☐ **Databases + Prescriber-supplied**

Purpose of Clinical Edit Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress clinical edit is used to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Clinical edit criteria assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical edit criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Setting & Population

- Drug class for review: Botulinum toxin type A (Botox®)
- Age range: All patients
- Gender: Male & female

Approval Criteria

- Therapy will be approved for the following indications:

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs
Blepharospasm	333.81	--
Spasmodic torticollis	333.83	--
Strabismus	378	--
Cerebral Palsy	343	--
Cervical Dystonia Torticollis, unspecified	723.5	--
Spastic Hemiplegia	342.11	--

- **Approvals for therapy for the following indications will be subject to review by a clinical consultant.**
    - **Diagnosis must be defined as "severe" – that is intolerable and interferes with daily activities.**

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs
Hyperhidrosis	**780.8**	**--**
Primary focal hyperhidrosis	**705.21**	**--**
Secondary focal hyperhidrosis	**705.22**	**--**

Denial Criteria

- Inappropriate Diagnosis
- **For Diagnosis of severe Hyperhidrosis, primary focal, or secondary focal:**
  - **Adequate trial and failure on anticholinergics**
  - **Adequate trial and failure on drying agents**

Required Documentation

Laboratory results:	☐	Progress notes:	☐
MedWatch form:	☐	Other:	☐

Disposition of Edit

- **Denial:** Exception 682 "Clinical Edit"

References

1. Allergen Pharmaceuticals Ireland. Botox prescribing information. Irvine, CA. July 2002. Accessed online June 9, 2003 at http://www.botox.com/site/.
2. Drug Facts and Comparisons, p. 1234-37, 2003.
3. Mayer, NH., Simpson DM. "Spasticity, Etiology, Evaluation, Management and the Role of Botulinum Toxin", We Move. September 2002.
4. Allergen Pharmaceuticals Ireland. Botox Notification Letter. Irvine, CA. October 2004.